Secretary's review process for an individual upon a showing of good cause (e.g., public health or agricultural emergencies, national security, impending expiration of a research grant, a short-term visit by a prominent researcher). To apply for an expedited review, an entity must submit a request in writing in accordance with §73.21 to the HHS Secretary establishing the need for such action. The HHS Secretary will provide a written decision granting the request, in whole or in part, or denying the request.

§73.9 Responsible Official.

(a) As a condition of conducting activities regulated under this part, an entity must identify and authorize an individual as the Responsible Official. The Responsible Official may identify one or more individuals, any of whom may serve as the Alternate Responsible Official when the Responsible Official is unavailable. The Responsible Official and all individuals identified to serve as the Alternate Responsible Official must meet all of the qualifications for a Responsible Official. The Responsible Official and all Alternate Responsible Officials must:

(1) Be approved under §73.8;

(2) Be familiar with the requirements of this part; and

(3) Have authority and responsibility to ensure that the requirements of this part are met, on behalf of the entity.

(b) For purposes of this part, the Alternate Responsible Official acting in the absence of the Responsible Official may conduct all of those activities required under this part to be performed by the Responsible Official.

(c) The Responsible Official is responsible for ensuring compliance with the regulations, including:

(1) Developing and implementing safety, security and emergency response plans in accordance with §73.10—§73.12;

(2) Allowing only approved individuals to have access to select agents or toxins in accordance with §73.8 and §73.11;

(3) Providing appropriate training for safety, security and emergency response in accordance with §73.13;

(4) Transferring select agents or toxins in accordance with §73.14;

(5) Providing timely notice of any theft, loss, or release of a select agent or toxin in accordance with §73.13;

(6) Maintaining detailed records of information necessary to give a complete accounting of all activities related to select agents or toxins in accordance with §73.15.

(7) The reporting of the identification of a select agent or toxin as a result of diagnosis, verification or proficiency testing in accordance with §73.6.

§73.10 Safety.

(a) An entity subject to the provisions of this part, must develop and implement a safety plan. In developing a safety plan, an entity should consider:

(1) The biosafety standards and requirements for BSL 2, 3, or 4 operations, as they pertain to the respective select agents, that are contained in the CDC/NIH publication, "Biosafety in Microbiological and Biomedical Laboratories," including all appendices except Appendix F. Copies may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Post Office Box 371954, Pittsburgh, Pennsylvania, 75250–7954 or call in the Washington, DC metropolitan area 202–512–1800 or outside that area call toll free 1–866–512–1800. Copies may be inspected at the Centers for Disease Control and Prevention, 1600 Clifton Road, Mail Stop E–79, Atlanta, Georgia. This publication is also available on the CDC Web site at *http://www.cdc.gov*.

(2) The specific requirements for handling toxins found in 29 CFR 1910.1450, "Occupational Exposure to Hazardous Chemicals in Laboratories" and/or 29 CFR 1910.1200, "Hazard Communication," whichever applies and specific provisions for handling toxins found in Appendix I in the CDC/NIH publication, "Biosafety in Microbiological and Biomedical Laboratories,"

(3) For provisions of the safety plan relating to genetic elements, recombinant nucleic acids and recombinant organisms, the "NIH Guidelines for Research Involving Recombinant DNA Molecules," (NIH Guidelines). This includes, among other things, provisions regarding risk assessment, physical containment, biological containment, and local review and applies to all recombinant DNA research, regardless of